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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/777,295	02/12/2004	Delbert E. Day	UMO 1553.3	5755

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SENNIGER POWERS LLP
100 NORTH BROADWAY
17TH FLOOR
ST LOUIS, MO 63102

EXAMINER	
HELM, CARALYNNE E	

ART UNIT	PAPER NUMBER
1615	

NOTIFICATION DATE	DELIVERY MODE
01/23/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

uspatents@senniger.com

Office Action Summary	Application No.	Applicant(s)	
	10/777,295	DAY ET AL.	
	Examiner	Art Unit	
	CARALYNNE HELM	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 September 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7 and 55-83* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7 and 55-83* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Upon further consideration and in light of new prior art, the finality of the previous office action is hereby withdrawn.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 55-65 and 68 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 6-7 of U.S. Patent No. 6,709,744. Although the conflicting claims are not identical, they are not patentably distinct from each other because both claim a particle with hydroxyapatite that is in shaped form. Instant claims 55-65 are recited as product-by-process claims. "[E]ven

though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) MPEP 2113. Although instant claim 55 requires that the final product take on the shape of the molded (shaped) water-soluble glass, no particular shape is required. Thus no structure is added by the limitations regarding the glass. Therefore claims 55-65 and 68 are obvious over claims 1 and 6-7 of U.S. Patent No. 6,709,744.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-4, 55-65, and 67 are rejected under 35 U.S.C. 102(b) as being anticipated by Brown (WO96/29144).

Instant claims 1, 3-4, 55-65, and 67 are recited as product-by-process claims. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a

product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) MPEP 2113. Although both instant claim 1 and 55 require that the final product take on the shape of the water-soluble glass, no particular shape is required. Thus no structure is added by the limitations regarding the glass bodies.

Brown teaches an agglomerate/shaped body of calcium phosphate particles (see example 1; instant claim 1). The particles used to make the agglomerates are at minimum 1 μm in diameter (see page 24 lines 20-31; instant claims 3-4). Thus the smallest agglomerate would contain at least two particles and measure at least 2 μm. After the calcium phosphate agglomerates are made, Brown teaches their immersion in aqueous liquid and conversion of these agglomerates into hydroxyapatite (see page 25 lines 19-25; instant claims 55-65 and 67). Therefore claims 1, 3-4, 55-65, and 67 are unpatentable over Brown.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The four factual inquiries of Graham v. John Deere Co. have been fully considered and analyzed in the rejections that follow.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-7 and 67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Day et al (US Patent No. 6,358,531 - see IDS).

Instant claims 1-7 and 67 are recited as product-by-process claims. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a

product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) MPEP 2113. Although both instant claim 1 and 55 require that the final product take on the shape of the water-soluble glass, no particular shape is required. Thus no structure is added by the limitations regarding the glass bodies.

Day et al. teaches porous, hollow shell particles that formed on the surface of solid borate based glass templates that dissolve away (see column 3 lines 56-64 and column 5 line 66-column 6 line 2; instant claims 5-7). The particles are taught to be irregularly shaped or an assemblage of microspheres (agglomerate) (see column 6 lines 5-8; instant claims 1 and 4). The particles are taught to range in size form 5 μm to 1000 μm (see column 6 lines 9-10; instant claim 3). In addition, Day et al. teach calcium and phosphorous (calcium phosphate) being in the particle products and the suitability of these structures for in vivo bone growth and as bone repair agents (see column 6 lines 29-32 and column 7 lines 35-38; instant claims 1, 4, and 67). Since the particles of Day et al. are shells that form on the outside of the glass template structures, the number of glass structures will determine the number of calcium phosphate bodies in the final product. The particular end use and final size desired for the particles can be readily determined by one of ordinary skill in the art, thus the number of calcium phosphate bodies in each particle would have been matter of routine experimentation at the time of

the invention (see instant claim 2). Therefore claims 1-7 and 67 are obvious over Day et al.

Claims 55-65 and 68-83 are rejected under 35 U.S.C. 103(a) as being unpatentable over Day et al. as applied to claims 1-7 and 67 above, and further in view of Hayakawa et al.(Journal of the American Ceramics Society 1999:2155-2160).

The process of making the calcium phosphate particles taught by Day et al. requires that the borate based glass (exemplified as 11.25% Li_2O, 78.75% B_2O_3, and 10% CaO) be soaked in a phosphate containing solution, such as a saline or body fluid (see column 8 lines 31-45; instant claims 69-74). The reaction of Ca from the glass with hydroxide and/or phosphate ions from the solution forms the particle structure (see column 4 lines 3-19). The structure forms on the glass surface, taking on its shape and gradually dissolving the glass away as the reaction product forms (see column 4 lines 3-19). Day et al. exemplify the immersion of the glass into a phosphate buffered saline solution where there is a 0.3M inorganic ion concentration and the solution temperature is 37°C (see column 7 lines 35-38 and column 8 lines 1-8; instant claims 68, 77-78, and 81-82). The reaction rate depends upon the metal oxide incorporated into the glass which coupled with the size of the glass being reacted, determines the time for immersion. Since the particles can be from 5 to 1000 μm and the reaction rate for CaO is 7 μm/h, the reaction/immersion time ranges from slightly less than an hour to 6 days (see column 8 lines 31-45; instant claims 75-76). Day et al. does not explicitly teach that

the form of calcium phosphate in the formed particles is hydroxyapatite or that the pH of the immersion solution used in the process.

Hayakawa et al. teach the formation of apatite on the surface of calcium containing sodium silicate glass upon soaking for several hours to days in simulated body fluid that contains phosphate ions (see section II paragraph 1 and table III). It was known that soaking borate based glass in saline or body fluid forms surface calcium phosphate (the base constituents of hydroxyapatite) and both hydroxide and phosphate ions react with the calcium in the glass based on the teachings of Day et al. This together with the knowledge that soaking silicate based glass in body fluid forms surface apatite from Hayakawa et al. would have made it obvious to one of ordinary skill in the art at the time of the invention to form hydroxyapatite in the invention of Day et al. (given optimization of the appropriate molar ratios and incubation time). Since Day et al. teach the utility of their particles in bone applications and hydroxyapatite is a very well known form of calcium phosphate used in such applications, one of ordinary skill in the art would have found it obvious to optimize the immersion time and ion proportions in the immersion solution to obtain this form of calcium phosphate (see instant claims 55-65). Further, since physiological fluids are known for the process taught by Day et al. (e.g. body fluid), it would have been obvious to set the pH of the immersion solution to that of body fluid, namely neutral pH (also interpreted to correspond "about 9"; see instant claims 79-80 and 83). Therefore claims 55-65 and 68-83 are obvious over Day et al. in view of Hayakawa et al.

Claims 55 and 66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Day et al. in view of Hayakawa et al. as applied to claims 55-65 and 68-82 above, and further in view of Jin et al. (Journal of Biomedical Materials Research 2000:491-499).

Day et al. in view of Hayakawa et al. make obvious the hydroxyapatite particle of instant claim 55 but do not teach it to be shaped as a rod, bar, cube, or ellipsoid. Jin et al. teach that hydroxyapatite particles were known to be shaped in rod form for bone applications (see page 491 column 1 paragraph 1 and page 492 column 2 paragraph 1). Since Day et al. specifically teach their particles for use in in vivo bone applications, it would have been obvious to one of ordinary skill in the art at the time of the invention to shape the particles of Day et al. in view of Hayakawa et al. in rods. Therefore claims 55 and 66 are obvious over Day et al. in view of Hayakawa et al. and Jin et al.

Response to Arguments

Applicant's arguments submitted September 2, 2008 have been considered but are moot in view of the new rejections. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CARALYNNE HELM whose telephone number is

(571)270-3506. The examiner can normally be reached on Monday through Thursday 8-5 (EDT).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Caralynne Helm/
Examiner, Art Unit 1615

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615